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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,422	11/13/2003	Mahmoud M. Abdel-Monem	P05844US01	9957

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EXAMINER	
OH, TAYLOR V	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,422	ABDEL-MONEM ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

It is noted that applicants have filed an Appeal Brief after the Final Rejection on 4/13/05; as a result of the appeal conference, the examiner has withdrawn the previous Office Action and reopened the prosecution of the application.

The Status of Claims

Claims 1-2 are pending.

Claims 1-2 have been rejected.

DETAILED ACTION

1. Claims 1-2 have been under consideration.

Priority

2. It is noted that the application is a division of 10/272,382 filed on 10/16/2002.

Drawings

3. None.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 , the phrase " an essential trace element " is recited. The expression of " an essential trace element " of an animal is ambiguous because in view of the absence of a definite animal species and its explicit nutritional requirement of the trace element, the scope of the claim can not be certain. Therefore, an appropriate correction is required.

In claim 1 , the phrase " a small but nutritional supplementation effective amount" is recited. The expression is vague and indefinite because the terms " a small" and "effective amount" do not state how small the effective amount can be effective in the claim. Therefore, an appropriate correction is required.

In claim 1 , the phrase " a 1:1 neutral complex of an essential trace element and a dicarboxylic alpha amino acid " is recited. The expression of " a 1:1 neutral complex " is vague and indefinite because it may mean the ratio of volume , mass , or molarity between the two compounds and also it is uncertain as to what it is meant by the neutral complex, which can be interpreted as the composition or the product of the compounds. Therefore, an appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 1-2, the phrase " an essential trace element... to an animal " is recited. However, the specification has not described enough information about what is meant by the phrase " an essential trace element... to an animal " because not all the animals require the same essential elements for maintaining their heath; for example, a horse, a cattle , and a sheep must need calcium, phosphorus, sodium, iron, zinc, cobalt and selenium in their diet ,whereas a rabbit does not need them at all as the nutrient requirements as shown in Maynard et al (see table 14.4) (Animal Nutrition, 7th ed., p.411); similarly, the same argument about the nutrient requirements can be applied to human beings shown in Remington's Pharmaceutical Sciences (see page 1005) (18th ed. , 1990, Mack Pub. Com.) in comparison with the other animals. Therefore, the specification has failed to describe the written description about the requirements of essential trace elements with respect to various animals.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-2 are rejected under 35 U.S.C. 102(a) as being anticipated clearly Kirschner et al (U.S. 6,352,713).

Kirschner et al discloses a method for providing a prenatal nutritional supplement containing ferrous glutamate (see col. 12 ,lines 9-10) to pregnant women. Furthermore, the nutritional supplement can be a chewable dosage form and the composition contains Fe present in an amount of from 10 mg to 200 mg (see col. 12 ,lines 14-15). and one of the intended usages is the animal feed(see col. 8 ,lines 65-66). This is identical with the claims.

2. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated clearly Henry , Jr. et al (US 6,358,544).

Henry , Jr. et al discloses a zinc aspartate compound (see col. 7 ,lines 13-16) to be used in the beverage dry mix (see col. 7 ,lines 16-27). This is identical with the claim.

3. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated clearly Nikiforov et al (N.E. Baumana (1971), 108, p. 182-4).

Nikiforov et al discloses a feed for hens containing a casein complex with zinc glutamate in order to show Al, Barium, and silicon in the egg albumin (see abstact page). This is identical with the claims.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated clearly Godfrey (US 4,684,528).

Godfrey discloses a zinc supplement containing zinc aspartate compound (see col. 3 ,lines 47-50) to be used for oral usage with no aftertaste (see col. 3 ,lines 15-17). This is identical with the claim.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated clearly Kaczmarczyk et al (Verhandlungen der Deutschen Gesellschaft fuer Innere Medizin, 1974, 80 , p.1274-1277).

Kaczmarczyk et al discloses the parental administration of magnesium chloride and magnesium aspartates, such as Mg L-aspartate, Mg DL-aspartate to magnesium deficient rats (see abstract page). This is identical with the claim.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any

inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims I-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (US 6,323, 354).

Moore teaches that a method for preparing amino acid transition metal chelates as a palatable highly bioavailable source for transition metals for animal nutrition from lipoproteins comprising nucleoprotein , nucleic acids ,keratins, collagen , and glutamic acid (see col. 8 ,lines 29-33) and transition metal salts selected from the group consisting of iron, zinc, copper, magnesium , and etc. (see col. 4 , lines 55-58).

> The product of Example 1, containing 9.55 weight percent zinc was fed at a rate of 1.8 grams of product per head per day to feedlot beef cattle with no sign of feed rejections. A still higher feed rate of 4.0 grams of product was fed to a lactating dairy herd with good palatability of the feed containing the chelate product observed. (see col. 7 ,lines 1-6).

The instant invention, however, differs from the prior art in that the 1:1 neutral complex of an essential trace element and a dicarboxylic alpha amino acid is recited.

Even so, the reference does offer the following guidance for how to prepare amino acid transition metal chelates in the 1:1 neutral complex between them (see col. 3 ,lines 17-25):

> To effectively form the chelate, it is necessary to neutralize the aqueous sodium or potassium salts of the amino acids and fatty acids to a pH between 3 and 7. Then, the water soluble salts of transition metals may be reacted with the neutralized sodium or potassium salts of amino acids and fatty acids to provide between 1 and 3, and preferably between 1.8 and 2.5 molecules of amino acid per transition metal, thereby forming an aqueous mixture of amino acid transition metal chelates and fatty acids.

From this teaching, it is possible for the skilled artisan in the art to prepare the 1:1 neutral complex of the Fe element (see col. 4 , line 57) and the glutamic acid (see col. 8 ,line 33) because Moore expressly teaches the broad workable range of from 1 to 3 molecules of amino acid per transition metal. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to change from the prior art ratio to the claimed ratio by routine experimentation depending upon the weight of the animal by routine experimentation. This is because such a modification to be successful and feasible as the guidance (see col. 3 ,lines 17-25) shown in the prior art.

7. Claims I-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over ICN (A world of Biomemdical Products Catalogue, 1995, p. 1194).

ICN teaches a synthetic amino diet mixture for an animal comprising L-aspartic acid (0.34 %) , L-glutamic acid (3.41 %) , salt mixture containing

magnesium salt (9.98 %), copper salt (0.15%), zinc salt (0.02 %), iron salt (0.62 %), and etc. (see page 1194, right column). Furthermore, the prior art has offered guidance that the composition can be adjusted to pellet by adding dextrin and sucrose ingredients (see page 1194, right column).

The instant invention, however, differs from the prior art in that the 1:1 neutral complex of an essential trace element and a dicarboxylic alpha amino acid is recited.

Even so, the reference does offer the guidance that the synthetic amino diet composition can be adjusted depending on its use(see page 1194, right column). Furthermore, it is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality . In re Becker, 33 USPQ 33 (C.C.P.A. 1937). In re Russell, 439 F. 2d 1228, 169 USPQ 426 (C.C.P.A.). Therefore, it would have been obvious to the skilled artisan in the art to be motivated to change from the prior art ratio to the claimed ratio depending upon the use of the amino acid diet for any particular animal. This is because such a modification to be successful and feasible as the guidance (see page 1194, right column) shown in the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TVOh
6/23/05

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